A dissertation on

"IMPACT OF YOGA NIDRA ON COGNITIVE IMPAIRMENT: AN INTERVENTIONAL STUDY"

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Dissertation Submitted to
The Tamil Nadu Dr. M. G. R. Medical University, Chennai, Tamil Nadu
In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

YOGA

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2016 – 2019

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The Institutional Ethics Committee of Government Yoga and Naturopathy Medical College,reviewed and discussed the application for approval of the proposal "IMPACT OF YOGA NIDRA ON COGNITIVE IMPAIRMENT: AN INTERVENTIONAL STUDY", for project work submitted by Dr.K.S.DHAMODHINI, 2nd year M.D. YOGA, Post Graduate,

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ACKNOWLEGDEMENT

Foremost, I express my sincere gratitude to **Dr.Manavalan,** Principal, Govt. Yoga and Naturopathy College, Arumbakkam, Chennai-106 for giving me this opportunity to pursue my Post Graduation degree from this prestigious institute. I also extend my gratitude towards **Dr.S.T.Venkateswaran**, HOD, Division of Yoga & Physical Therapeutics, GYNMC, Arumbakkam, Chennai-106, for his constant support and encouragement. I also thank **Dr.R.S.Himeshwari** H.O.D. Acupuncture and Energy Medicine for her support. I express my heartfelt gratitude to **Dr.Kumaresan**, Assistant medical officer, Govt. Yoga and Naturopathy C ollege, Arumbakkam, Chennai-106 for for helping me throughout the statistical analysis and its interpretations needed for this study and also for guiding and encouranging me throughout the process. I also extend my gratitude to **Dr.Ramya**, Assistant medical officer, Govt. Yoga and Naturopathy College, Arumbakkam, Chennai-106 for guiding me in completing this dissertation. I also thank all the teaching and non-teaching staff of my institution for their support. I would like to dedicate this dissertation, and the ability to persevere and finish, to my Lord. I also thank my parents **Mrs.Kalavathi** and **Mr.T.P.Subramaniam** who was right by my side and who keeps on encouraging me and helping me throughout the process. I also thank my brothers **Mr.K.S.Thirugnanasambandam** and **Mr.K.S.Bharanikumar** for the encouragement, prayers, and moral support along the way. I also acknowledge the support of all the subjects who participated in the study.

Date: Dr.K.S.Dhamodhini

LIST OF ABBREVIATIONS USED

CI	Cognitive impairment
YN	Yoga nidra
MCI	Mild cognition impairment
AD	Alzhiemers disease
WHO	World Health Organisation
PSS	Perceived stress scale
SOD	Super oxide dismutase
MDA	Malondialdehyde
hs-CRP	High sensitivity C-reactive protein
AchE	Acetylcholinesterase
GSK-3	Glycogen synthase kinase - 3
VEGF	Vascular endothelial growth factor enzyme
BDNF	Brain derived neutrophic factor
MMP-9	Matrix metallo proteinase - 9

ABSTRACT

Objective: The intended research work aims at assessing the impact of yoga nidra on cognitive impairment and document the improvement in depression/ anxiety/ stress level in impaired subjects Many studies reported that the practice of yoga, especially relaxation tehniques influences Cognition. The current study was conducted to determine the positive effect of practicing 'Yoga nidra' to reduce/cure the severity of cognitive impairment by systematic reviewing, followed by monitoring MMSE score and also DASS score.

Study Design: The current research work employed prospective intervention study.

Method: 40 healthy volunteers belonging within the age group of 30 - 55 participated in the study. The study participants were given two months training on Yoga nidra. The study participants were instructed to practice Yoga nidra for 30 minutes on alternated days for 2 months. The MMSE scale score and DASS scores of participants were monitored before and after giving the intervention.

Result: The study showed a significant improvement in the cognition and decrease in the level of Depression, Anxiety and Stress in affected individuals

affected by cognitive impairment. MMSE score and DASS score of the study participants are significantly improved by the practice of yoga nidra on alternate days for 2 months

Conclusion: The practice of Yoga nidra facilitates in improving the cognition in individuals who has cognitive impairment by reducing depression, anxiety and stress levels of the individuals.

Keywords: Cognitive impairment, Depression, Anxiety, Stress, MMSE, DASS.

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1.0 INTRODUCTION

Cognition is a combination of skills that include attention, learning, memory, language, visuospatial skills and executive function such as decision making, goal setting, planning, and judgment. Older adults are the population most at risk for cognitive impairment.

Cognitive impairment is recognized as being either syndromic (eg, MCI, subjective cognitive decline, mild neurocognitive disorder, or cognitive frailty) or etiologic (eg, prodromal AD or early symptomatic AD)(2)

Establishing an early diagnosis enables elderly and their family members adjust to the diagnosis and middle prepare for the future in an appropriate way.(3), (4)

Older people frequently have multiple health conditions such as chronic physical diseases coexisting with mental or cognitive disorders, the effects of which may combine together in complex ways leading to disability and needs for care. However, studies from both high-income countries (5)(6)and low- and middle income countries concur that, among older people, cognitive impairment and dementia make the largest contribution to needs for care, much more so than other types of impairment and other chronic diseases.(7), (8)

Dementia and cognitive impairment are the leading chronic disease contributors to disability, and, particularly, dependence among older people worldwide. While older people can often cope well, and remain reasonably independent even with marked physical disability, the onset of cognitive

impairment quickly compromises their ability to carry out complex but essential tasks in daily life. In addition, people living with dementia will increasingly have difficulty to meet their basic personal care needs.(9)

Some research has shown a relationship between the development of cognitive impairment and life-style related risk factors that are shared with other non communicable diseases. These risk factors include physical inactivity, obesity, unhealthy diets, tobacco use and harmful use of alcohol, diabetes, and midlife hypertension. Additional potentially modifiable risk factors include depression, low educational attainment, social isolation, and cognitive inactivity(10)

Cognitive impairment is when a person has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life. Cognitive impairment ranges from mild to severe. With mild impairment, people may begin to notice changes in cognitive functions, but still be able to do their everyday activities. Severe levels of impairment can lead to losing the ability to understand the meaning or importance of something and the ability to talk or write, resulting in the inability to live independently.(11) Cognitive impairment prevalence also increases with increasing age. (12),(13)

As such, there is scarcity of prevalence studies from Northern India due to ethnic and sociocultural diversities. There is regional variation in prevalence of cognitive decline as well as risk factors from region to region.(14)

Epidemiological studies of dementia in person ≥60 years in urban and rural population of southern India had obtained prevalence rates of 27-33.6/1000 and 34-36/1000, respectively. (15),(16),(17)

It was subsequently described as memory loss without associated decline in cognitive functioning or daily functioning that does not meet diagnostic criteria for dementia. Most Chinese researchers use the following definition for MCI, a clinical condition between natural aging and mild dementia characterized by memory loss with or without mild cognitive dysfunction which does not affect the individual's social and daily functioning and that is not explained by other nervous system conditions, mental disorders, or other known medical diseases(111).

Aging is associated with the decline in cognition and older adults may have demonstrable cognitive impairment but not crossing the threshold for dementia.(112)

While monitoring the cognition of currently depressed and previously depressed subjects, it is found that both currently depressed and previously depressed scored significantly lower than never depressed subjects. Recurrently depressed subject's shows similarly to subjects with a single depressive episode. These outcomes indicate a mild and limited cognitive impairment during the course of a mild to moderate major depressive disorder even in young adults(129).

A study which evaluated the association between CI and MDD, in which participants were assessed clinically using the Mini International Neuropsychiatric Interview (M.I.N.I.) for the depression groups and the Diagnostic Interview for Psychoses (DIP-DM) for the control group(n=206). Measures to evaluate cognition and quality of lifes comprised the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), the Short Form-36 Health Survey Questionnaire, and the Activities/Instrumental Activities of Daily Living (ADL/IADL); employment status was also assessed in MDD. The results showed that while individuals with current depression had worse cognitive performance in all domains than healthy controls, those individuals with previous depression had lasting cognitive impairments in the domains of immediate memory and attention as compared with healthy controls.

Yoga is regarded as one of the major disciplines that primarily concentrate on the well-being of the individual, both physically and mentally. The practice of yoga concerns mainly on integrating every aspects that are vital for self-realization and adopting a healthier lifestyle. Yoga postures facilitates in improving the physical condition, when practiced with utmost precision, involving a controlled and rhythmic motion of our body, of which breath control is of paramount importance.

"Yoga is the control of the patterns of consciousness." (18)

The word yoga means ‘unity’ or ‘oneness’ and is derived from the Sanskrit word ‘Yuj’, which means to join. This unity or joining is described in spiritual terms as the union of the individual consciousness with the universal consciousness.(19)

Yogic (relaxation) techniques offer a means to reduce the physiological and psychological reactions to stress. (20),(21) Yoga is one of the many popular techniques for achieving relaxation. Its original form consisted of spiritual, moral and physical practices.(22)

Yoga Nidra means sleep with a trace of awareness. It is a state of mind in between wakefulness and dream. When you practice yoga nidra you are opening the deeper phase of your mind. (19)(23)

Researches also indicate that Yoga Nidra can be used as a therapeutic technique to cure psychological disorders like anxiety, hostility, insomnia etc, and psychosomatic diseases like asthma, coronary heart disease, cancer, hypertension etc. Yoga Nidra is a successful therapy for both recent and longstanding psychological disturbances of all kinds, especially high anxiety levels and neurotic behavior patterns. (24)

The many studies show that the yoga has huge impact on improving mental health and memory. The studies in older adults reveal that Yoga is helpful in preventing cognitive decline, focused attention and improve working memory performance. (25)

An 8-week meditation program resulted in improvements in neuropsychological function. (26) Kirtan Kriya yoga intervention showed that effective in improving memory functions and functional connectivity-related to verbal, attention, and self-regulatory performance. (27)

Our study aimed to assess the impact of yoga on cognitive impairment as well as assess the association of the demographic variables and cognitive impairment.

In another study it is proved that the depressed group with melancholia has a distinctly different and more impaired cognitive profile compared to those without melancholic features. Moreover, the melancholic group seems to require longer periods for cognitive recovery and this has implications for return to work and daily functioning following clinical discharge(128).

Another study showed the effectiveness of *Yoga Nidra* and seated meditation in reducing anxiety and stress levels of college professors when compared to the control group, there was greater effectiveness of the Yoga Nidra intervention, regarding anxiety.(149)

From a review article, it is concluded that yoga nidra helps in various mental health problems and also good for general wellbeing(150).So mental health problems can be treated with yoga nidra alone for complete cure.

A study conducted on 100 women with depression and anxiety linked to menstruation showed that the intervention group has been benefited from yoga nidra than the control group. Hence they have concluded that YN practice is beneficial for anxiety, depression and stress.(148)

Another study proved that Yoga nidra can be a successful therapy to overcome the psychiatric morbidity associated with menstrual irregularities and other psychosomatic disorders.(151)

A research have proved that intervention group which practiced yoga nidra for six months, showed significant decrease in the degree of depressive symptoms, those symptoms are calculated according to the psychological general wellbeing Index.(152)

Study by rani et al proved that Yoga Nidra is a successful therapy to overcome the psychiatric morbidity and so it can be prescribed as an adjunct to conventional drug therapy for menstrual dysfunction.(148)

2.0 AIMS AND OBJECTIVES

2.1 AIM

To assess the effect of Yoga Nidra practices on cognitive impairment subjects.

2.2 OBJECTIVES

Primary objective:

- To assess the impact of Yoga Nidra on cognitive impaired subjects

Secondary objective:

- To document the improvement in depression/ anxiety/ stress level in impaired subjects.

3.0 REVIEW OF LITERATURE

3.1 Cognition

Although the term cognition has a long history dating back to the ancient Greeks.(28)

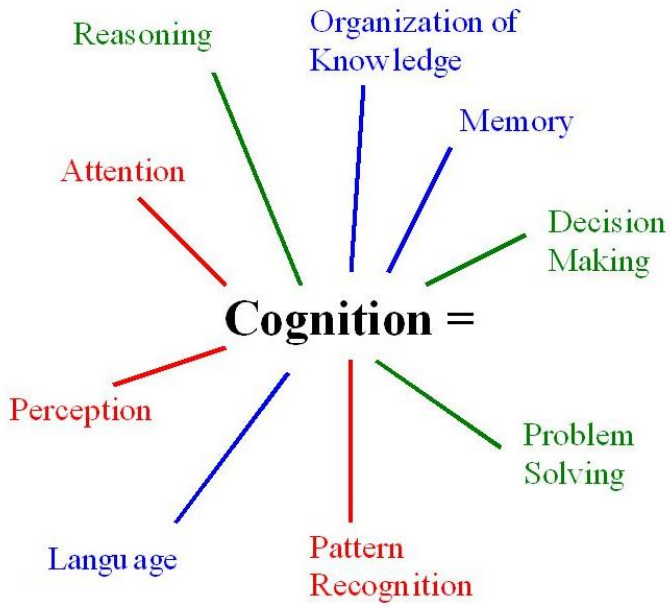


Figure 1: Representation the domains of cognition

About 50 years ago, Neisser in his seminal textbook on cognitive psychology: defined cognition as the term 'cognition' refers to all the processes by which the sensory input is transformed, reduced, elaborated, stored, recovered, and used. It is concerned with these processes even when they operate in the absence of relevant stimulation, as in images and hallucinations .Thus, it is apparent that cognition is involved in everything a human being might possibly do; that every psychological phenomenon is a cognitive phenomenon. (29)

Neisser (1967) views cognition as information processing. This is a mental perspective in so far as the mind is considered to be informational in nature. (30)

Gardner (1987) has noted that linking cognition and the mind to information shapes out a new level of explanation at which cognitive psychologists can drive. To fully appreciate the importance of this idea, one has to realize that information can be deliberated of as nonphysical in nature.(31)

Neisser defines cognition as a dynamic process. This dynamic process can be marked as a mental mechanism, that is, a chain of information processing steps cognition as information processing legitimized cognitive psychology as a separate science of the mental world.(32)

From a functional-analytic perspective, cognition is behavior.(33) Cognition may be understood both functional analytically as involving complex environment-behavior relations along with term of information processing that mediate those environment-behavior relations. On the contrary, within a functionalcognitive framework close interactions between functional and cognitive research could, in principle, lead to a better understanding of cognition in clinical psychology, whether it is defined in functional-analytical terms or in terms of information processing. This functional cognitive framework thus offers a new perspective on the long standing divide between functional and cognitive approaches in clinical psychology, and psychology more generally, and opens up

avenues for future interactions between researchers and practitioners from both sides of the divide. (34)

3.2.1 Cognitive psychology

Cognitive psychology is the study of how people perceive, learn, remember, and think about information. A cognitive psychologist might study how people perceive various shapes, why they remember some facts but forget others, or how they learn language.(35)

Cognitive psychology is based on two assumptions: (1) Human cognition can at least in principle be fully revealed by the scientific method, that is, individual components of mental processes can be identified and understood, and (2) Internal mental processes can be described in terms of rules or algorithms in information processing models. There has been much recent debate on these assumptions. (35), (36), (37)

3.2.2 History of Cognitive psychology

The intellectual origins of cognitive psychology began with cognitive approaches to psychological problems at the end of the 1800s and early 1900s in the works of Wundt, Cattell, and William James. (38)

Cognitive psychology declined in the first half of the 20th century with the rise of “behaviorism" which is the study of laws relating observable behavior to objective, observable stimulus conditions without any recourse to internal mental processes. (39), (38), (40) . Lack of understanding of the internal mental processes

led to no distinction between memory and performance and failed to account for complex learning. (41), (42). This issue led to the decline of behaviorism as the dominant branch of scientific psychology and to the “Cognitive Revolution”. The Cognitive Revolution began in the mid-1950s (43). Cognitive psychology became predominant in the 1960s(43) .

3.2.3 Approches towards Cognitive psychology

There are currently three main approaches in cognitive psychology: experimental cognitive psychology, computational cognitive psychology,and neural cognitive psychology. Experimental cognitive psychology treats cognitive psychology as one of the natural sciences and applies experimental methods to investigate human cognition. Psychophysical responses, response time, and eye tracking are often measured in experimental cognitive psychology.

Computational cognitive psychology develops formal mathematical and computational models of human cognition based on symbolic and subsymbolic representations, and dynamical systems. Neural cognitive psychology uses brain imaging (e.g., EEG, MEG, fMRI, PET, SPECT, Optical Imaging) and neurobiological methods (e.g., lesion patients) to understand the neural basis of human cognition. The three approaches are often inter-linked and provide both independent and complementary insights in every sub-domain of cognitive psychology. (38)

3.3 Domains of Cognitive Psychology

cognitive psychology includes perception, attention , learning , memory concept formation , reasoning , judgment and decision-making, problem solving, and language processing . For some, social and cultural factors, emotion, consciousness, animal cognition, evolutionary approaches have also become part of cognitive psychology. (39)

3.3.1 Perception

Those studying perception seek to understand how we construct subjective interpretations of proximal information from the environment. Perceptual systems are composed of separate senses (e.g., visual, auditory, somatosensory) and processing modules (e.g., form, motion) (44)and sub-modules(45)that represent different aspects of the stimulus information. Cognitive psychologists have studied these properties empirically with psychophysical methods and brain imaging. Computational models, based on physiological principles, have been developed for many perceptual systems (46) , (47).

3.3.2Attention

Attention solves the problem of information overload in cognitive processing systems by selecting some information for further processing, or by managing resources applied to several sources of information simultaneously (48), (49),(50). Empirical investigation of attention has focused on how and why attention improves performance, or how the lack of attention hinders performance (49) , (51), (52). The theoretical analysis of attention has taken several major

approaches to identify the mechanisms of attention: the signal-detection approach(53) and the similarity-choice approach(54), (55). Related effects of biased competition have been studied in single cell recordings in animals. Brain imaging studies have documented effects of attention on activation in early visual cortices, and have investigated the networks for attention control(56).

3.3.3Learning

Learning improves the response of the organism to the environment. Cognitive psychologists study which new information is acquired and the conditions under which it is acquired. The study of learning begins with an analysis of learning phenomena in animals (i.e., habituation, conditioning, and instrumental, contingency, and associative learning) and extends to learning of cognitive or conceptual information by humans(57), (58), (59) .

Cognitive studies of implicit learning emphasize the largely automatic influence of prior experience on performance, and the nature of procedural knowledge(60). Studies of conceptual learning emphasize the nature of the processing of incoming information, the role of elaboration, and the nature of the encoded representation (61). Those using computational approaches have investigated the nature of concepts that can be more easily learned, and the rules and algorithms for learning systems (62). Those using lesion and imaging studies investigate the role of specific brain systems (e.g., temporal lobe systems) for certain classes of episodic learning, and the role of perceptual systems in implicit learning (63) , (64), (65).

3.3.4 Memory

The study of the capacity and fragility of human memory is one of the most developed aspects of cognitive psychology. Memory study focuses on how memories are acquired, stored, and retrieved. Memory domains have been functionally divided into memory for facts, for procedures or skills, and working and short-term memory capacity. The experimental approaches have identified dissociable memory types (66)or capacity limited processing systems such as short-term or working memory(67) . Computational approaches describe memory as propositional networks, or as holographic or composite representations and retrieval processes(68), (69). Brain imaging and lesion studies identify separable brain regions active during storage or retrieval from distinct processing systems (70).

3.3.5 Concept Formation

Concept or category formation refers to the ability to organize the perception and classification of experiences by the construction of functionally relevant categories. The response to a specific stimulus is determined not by the specific instance but by classification into the category and by association of knowledge with that category(71).

The ability to learn concepts has been shown to depend upon the complexity of the category in representational space, and by the relationship of variations among exemplars of concepts to fundamental and accessible dimensions of representation(72). Certain concepts largely reflect similarity structures, but

others may reflect function, or conceptual theories of use(73). Computational models have been developed based on aggregation of instance representations, similarity structures and general recognition models, and by conceptual theories(74). Cognitive neuroscience has identified important brain structures for aspects or distinct forms of category formation. (75).

3.3.6. Judgment and decision:

Human judgment and decision making is ubiquitous – voluntary behavior implicitly or explicitly needs judgment and choice. The historic foundations of choice are based in normative or rational models and optimality rules, beginning with expected utility theory(76) .

Extensive analysis has identified widespread failures of rational models due to differential assessment of risks and rewards(77), the partial assessment of probabilities(78),and the limitations in human information processing. New computational approaches rely on dynamic systems explores of judgment and choice (79)and Bayesian belief networks that make choices based on multiple criteria(80)for more complex situations. The study of decision making has become an energetic topic in cognitive neuroscience(81).

3.3.7. Reasoning

Reasoning is the process by which logical arguments are evaluated or constructed. Original investigations of reasoning attentive on the extent to which humans correctly applied the philosophically derived rules of inference in deduction, and the many ways in which humans fail to appreciate some

conclusions and falsely conclude others. These were extended to margins in reasoning with syllogisms or quantifiers(82). Inductive reasoning, in contrast, develops a hypothesis reliable with a set of observations or reasons by analogy(83). Often reasoning is affected by experimental judgments, fallacies, and the representativeness of evidence, and other framing phenomena (84). Computational models have been developed for inference making and analogy (83), logical reasoning, and Bayesian reasoning (85).

3.3.8. Problem Solving:

The cognitive psychology of problem solving is the study of how humans follow goal directed behavior. The computational state-space analysis and computer simulation of problem solving of Newell and Simon (1972) and the empirical and experimental analysis of Wickelgrentogether have set the cognitive psychological approach to problem solving. Solving a problem is considered as finding operations to move from the initial state to a goal state in a problem space using either algorithmic or experimental solutions. The problem depiction is critical in finding solutions(86). Expertise in knowledge rich fields (i.e., chess) also depends on complex pattern recognition(87). Problem solving may involve perception, memory, attention, and executive function, and so many brain areas may be engaged in problem solving tasks, with an highlighting on pre-frontal executive functions.

3.3.9. Language Processing:

While etymological approaches focus on the formal structures of languages and language use(42), cognitive psychology has concentrated on language acquisition, language comprehension, language production, and the psychology of reading(88). Psycholinguistics has studied encoding and verbal access of words, sentence level processes of describing and representation, and general representations of concepts, gist, inference, and semantic expectations. Computational models have been developed for all of these levels, including verbal systems, parsing systems, semantic representation systems, and reading aloud(89). The neuroscience of language has a long history in the analysis of lesions(90)and has also been widely studied with cognitive imaging(49).

3.4 Cognitive Neuroscience

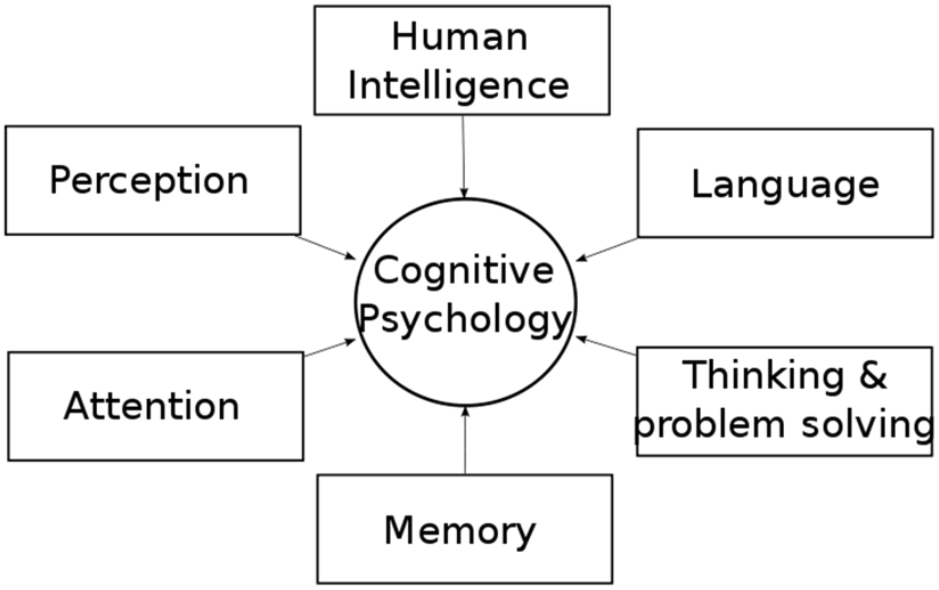


Figure 2: Representation of Cognition psychology

Cognitive neuroscience is the field of study linking the brain and other aspects of the nervous system to cognitive processing and, ultimately, to behavior. The brain is the organ in our bodies that most directly controls our thoughts, emotions, and motivations(90). Figure 3 shows photos of what the brain actually looks like. We usually think of the brain as being at the top of the body's hierarchy—as the boss, with various other organs responding to it. Like any good boss, however, it listens to and is influenced by its subordinates, the other organs of the body. Thus, the brain is reactive as well as directive.(91)

3.4. Cognition in the Brain: The Anatomy and Mechanisms of the Brain:

3.4.1: Gross Anatomy of the Brain: Forebrain, Midbrain and Hindbrain

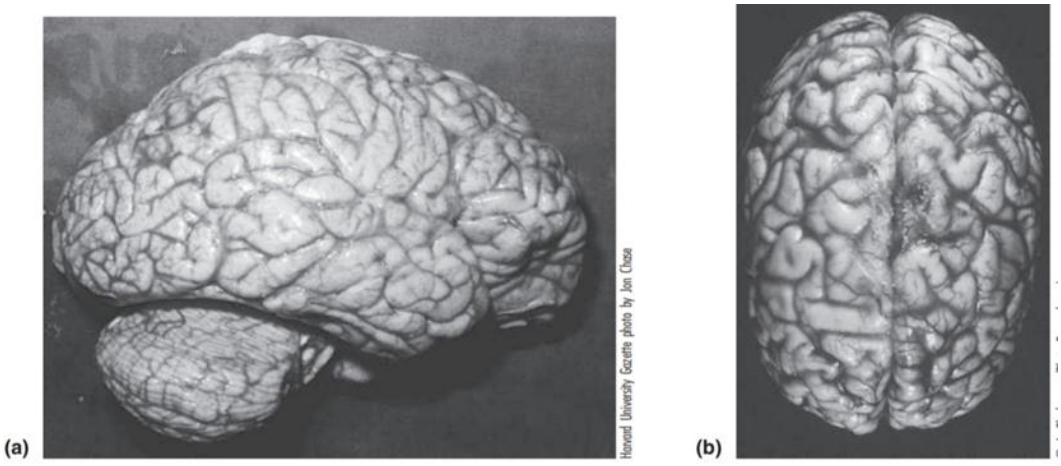


Figure 3: Representation of brain (a) side view and (b) top view

3.4.1.1 The Forebrain:

The forebrain is the region of the brain located toward the top and front of the brain. It comprises the cerebral cortex, the basal ganglia, the limbic system, the thalamus, and the hypothalamus.

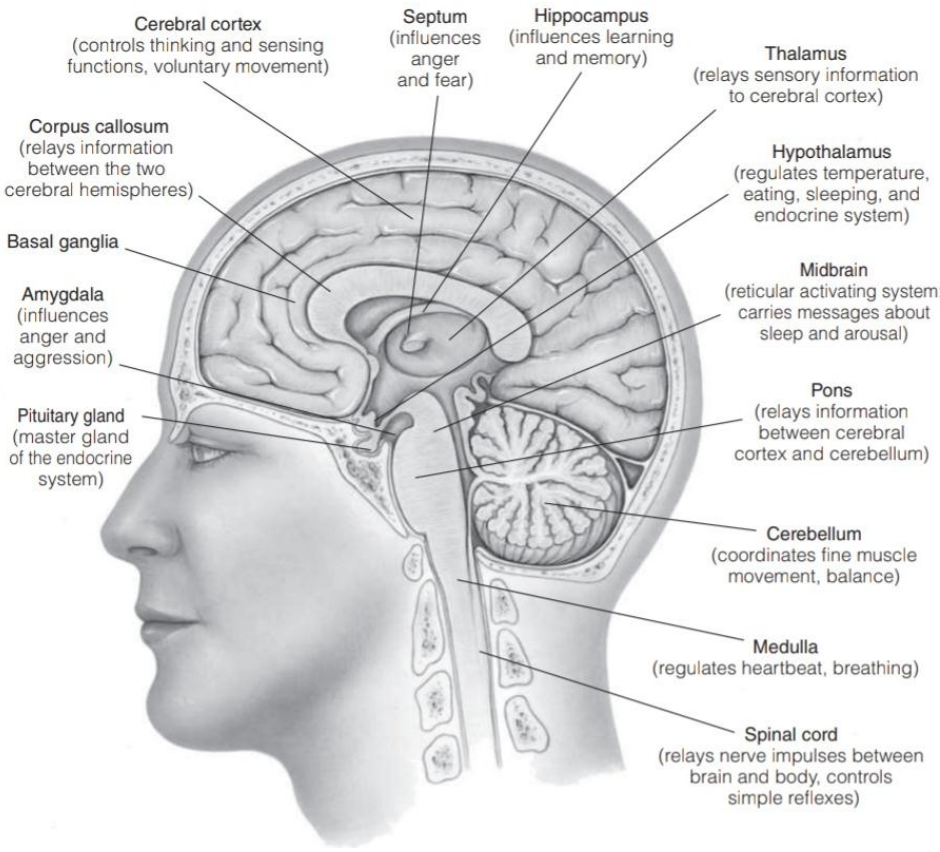


Figure 4: Structures of the Brain.

The cerebral cortex is the outer layer of the cerebral hemispheres. It plays a vital role in our thinking and other mental processes. It therefore merits a special section in this chapter, which follows the present discussion of the major structures and functions of the brain.

The basal ganglia are collections of neurons crucial to motor function. Dysfunction of the basal ganglia can result in motor deficits. These deficits include tremors, involuntary movements, changes in posture and muscle tone, and slowness of movement. Deficits are observed in Parkinson's disease and Huntington's disease. Both these diseases entail severe motor symptoms(92)(93).

The limbic system is important to emotion, motivation, memory, and learning. Our limbic systems help us to adapt our behaviors flexibly in response to our changing environment. The limbic system comprises three central interconnected cerebral structures: the septum, the amygdala, and the hippocampus.

The septum is involved in anger and fear. The amygdala plays an important role in emotion as well, especially in anger and aggression (93). Stimulation of the amygdala commonly results in fear. It can be evidenced in various ways, such as through palpitations, fearful hallucinations, or frightening flashbacks in memory(94). Damage to or removal of the amygdala can result in maladaptive lack of fear. The amygdala also has an enhancing effect for the perception of emotional stimuli. The hippocampus plays an essential role in memory formation. The hippocampus is essential for flexible learning and for seeing the relations among items learned as well as for spatial memory (95). The hippocampus also appears to keep track of where things are and how these things are spatially related to each other. (96).

The thalamus relays incoming sensory information through groups of neurons that project to the appropriate region in the cortex. Most of the sensory input into the brain passes through the thalamus, which is approximately in the center of the brain, at about eye level. The thalamus also helps in the control of sleep and waking.

The hypothalamus regulates behavior related to species survival: fighting, feeding, fleeing, and mating. The hypothalamus also is active in regulating

emotions and reactions to stress(97). The hypothalamus plays a role in sleep. The hypothalamus also is important for the functioning of the endocrine system.

3.4.1.2 The midbrain:

The midbrain helps to control eye movement and coordination. By far the most indispensable of these structures is the reticular activating system which is also called the "reticular formation", a network of neurons essential to the regulation of consciousness such as sleep, wakefulness, arousal, attention and vital functions(98). The RAS also extends into the hindbrain. Both the RAS and the thalamus are essential to our having any conscious awareness of or control over our existence.

3.4.1.3 The Hindbrain:

The hindbrain comprises the medulla oblongata, the pons, and the cerebellum. The medulla oblongata controls heart activity and largely controls breathing, swallowing, and digestion. The medulla is also the place at which nerves from the right side of the body cross over to the left side of the brain and nerves from the left side of the body cross over to the right side of the brain.

The medulla oblongata is an elongated interior structure located at the point where the spinal cord enters the Reticular activating system (also extends into the hindbrain) Important in controlling consciousness (sleep arousal), attention, cardiorespiratory function, and movement Gray matter, red nucleus, substantia nigra, ventral region Important in controlling movement Hindbrain Cerebellum Essential to balance, coordination, and muscle tone Pons (also contains part of the

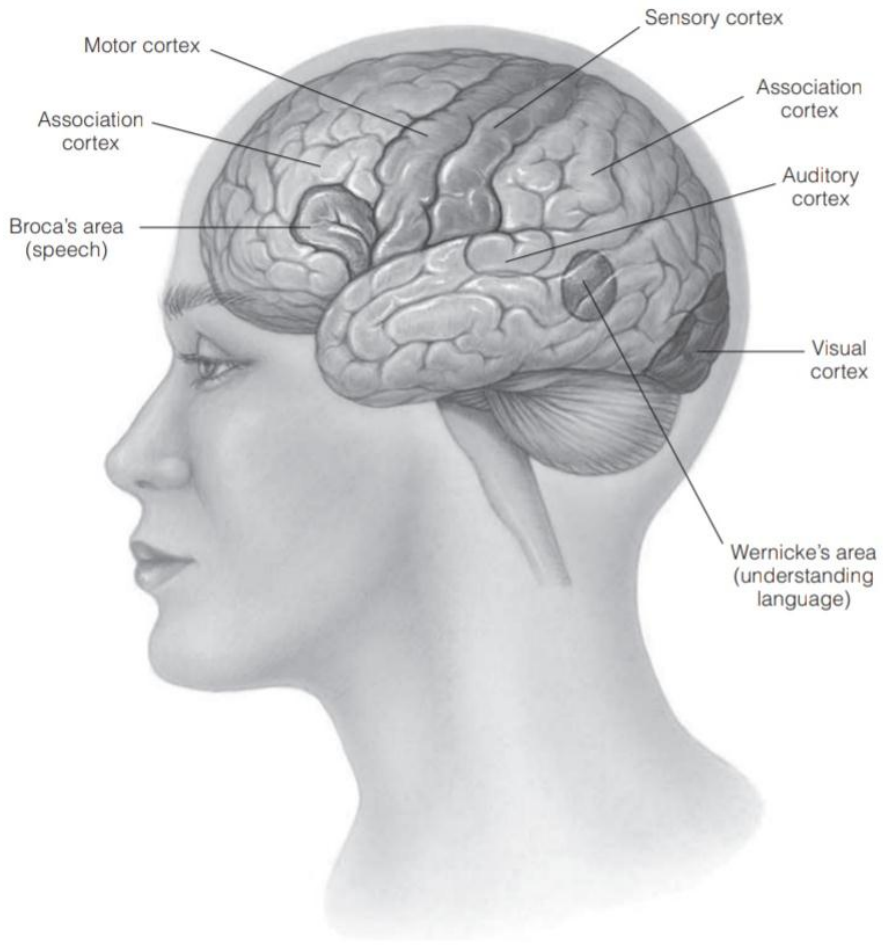
RAS) Involved in consciousness (sleep and arousal); bridges neural transmissions from one part of the brain to another; involved with facial nerves Medulla oblongata Serves as juncture at which nerves cross from one side of the body to opposite side of the brain; involved in cardiorespiratory function, digestion, and swallowing. The medulla oblongata, which contains part of the RAS, helps to keep us alive. (99)

The pons serves as a kind of relay station because it contains neural fibers that pass signals from one part of the brain to another. Its name derives from the Latin for "bridge," as it serves a bridging function. The pons also contains a portion of the RAS and nerves serving parts of the head and face.

The cerebellum controls bodily coordination, balance, and muscle tone, as well as some aspects of memory involving procedure-related movements(100). The prenatal development of the human brain within each individual roughly corresponds to the evolutionary development of the human brain within the species as a whole.

The cerebral cortex plays an extremely important role in human cognition. The cortex comprises 80% of the human brain(101). The corpus callosum is a

dense aggregate of neural fibers connecting the two cerebral hemispheres(102).



Figures 5: Functional areas of the cortex

Lobes of the Cerebral Hemispheres

The frontal lobe, toward the front of the brain, is associated with motor processing and higher thought processes, such as abstract reasoning, problem solving, planning, and judgment (103). It tends to be involved when sequences of thoughts or actions are called for. It is critical in producing speech. The prefrontal cortex, the region toward the front of the frontal lobe, is involved in complex motor control and tasks that require integration of information over time(104).

The parietal lobe, at the upper back portion of the brain, is associated with somato sensory processing. It receives inputs from the neurons regarding touch, pain, temperature sense, and limb position when you are perceiving space and your relationship to it—how you are situated relative to the space you are occupying(104). The parietal lobe is also involved in consciousness and paying attention. If you are paying attention to what you are reading, your parietal lobe is activated.

The temporal lobe, directly under your temples, is associated with auditory processing(105) and comprehending language. It is also involved in your retention of visual memories. For example, if you are trying to keep in memory,then your temporal lobe is involved. The temporal lobe also matches new things you see to what you have retained in visual memory.

The occipital lobe is associated with visual processing. The occipital lobe contains numerous visual areas, each specialized to analyze specific aspects of a scene, including color, motion, location, and form (104). When you go to pick strawberries, your occipital lobe is involved in helping you find the red strawberries in between the green leaves. Projection areas are the areas in the lobes in which sensory processing occur (104).

3.5 Monitoring the Structures and Functions of the Brain

3.5.1 Electrical Recordings

The transmission of signals in the brain occurs through electrical potentials. When recorded, this activity appears as waves of various widths (frequencies) and

heights (intensities). Electroencephalograms (EEGs) are recordings of the electrical frequencies and intensities of the living brain, typically recorded over relatively long periods(106). Through EEGs, it is possible to study brainwave activity indicative of changing mental states such as deep sleep or dreaming.

An event-related potential (ERP) is the record of a small change in the brain's electrical activity in response to a stimulating event. ERP can be used to examine developmental changes in cognitive abilities. These experiments provide a more complete understanding of the relationship between brain and cognitive development (107).

3.5.2 Static Imaging Techniques:

It is to reveal the structures of the brain. The techniques include angiograms, computed tomography (CT) scans, and magnetic resonance imaging scans (MRI). The X-ray–based techniques (angiogram and CT scan) allow for the observation of large abnormalities of the brain, such as damage resulting from strokes or tumors.

3.5.3 Computed tomography (CT or CAT):

Unlike conventional X-ray methods that only allow a two-dimensional view of an object, a CT scan consists of several X-ray images of the brain taken from different vantage points that, when combined result in a three-dimensional image.

3.5.4 Angiography:

The aim of an **angiography** is not to look at the structures in the brain, but rather to examine the blood flow. When the brain is active, it needs energy, which is transported to the brain in the form of oxygen and glucose by means of the blood. In angiography, a dye is injected into an artery that leads to the brain, and then an X-ray image is taken.

3.5.5 The magnetic resonance imaging (MRI)

It scan is of great interest to cognitive psychologists. The MRI reveals high-resolution images of the structure of the living brain by computing and analyzing magnetic changes in the energy ofthe orbits of nuclear particles in the molecules of the body. There are two kinds of MRIs structural MRIs and functional MRIs. Structural MRIs provide images of the brain's size and shape whereas functional MRIs visualize the parts of the brain that are activated when a person is engaged in a particular task. MRIs allow for a much clearer picture of the brain than CT scans (35).

3.6 Cognitive impairment

The concept of mild cognitive impairment (MCI) was first proposed by Reisberg in 1982(108). Cognitive impairment is when a person has trouble remembering, learning new things, concentrating, or making decisions that affect their everyday life. Cognitive impairment ranges from mild to severe. With mild impairment, people may begin to notice changes in cognitive functions, but still be able to do their everyday activities. Severe levels of impairment can lead to losing

the ability to understand the meaning or importance of something and the ability to talk or write, resulting in the inability to live independently(109).

Cognitive Impairment (CI) refers to deficits in attention, verbal and nonverbal learning, short-term and working memory, visual and auditory processing, problem solving, processing speed, and motor functioning. Cognitive dysfunction may be a primary mediator of functional impairment in MDD.(110)

It was subsequently described as memory loss without associated decline in cognitive functioning or daily functioning that does not meet diagnostic criteria for dementia. Most Chinese researchers use the following definition for MCI, a clinical condition between natural aging and mild dementia characterized by memory loss with or without mild cognitive dysfunction which does not affect the individual's social and daily functioning and that is not explained by other nervous system conditions, mental disorders, or other known medical diseases(111).

Aging is associated with the decline in cognition and older adults may have demonstrable cognitive impairment but not crossing the threshold for dementia.(112)

Table-1: Shows that the WHO criteria to screen and differentiate Cognitive impairment and Dementia and that criteria is named as Wilson's Criteria.

Table 1: Application of the World Health Organization (Wilson's Criteria) Screening Criteria to Cognitive Impairment and Dementia

	Cognitive Impairment	**Dementia**
1 The condition should be an important health problem	YES	YES
2 There should be treatment for the condition	Some	Slow Deterioration
3 Facilities for diagnosis and treatment should be available	Some	Some
4 There should be a latent stage of disease	Uncertain	YES
5 There should be a test or examination for the condition	YES	YES
6 The test should be acceptable to the population	YES	YES
7 The natural history of the disease should	Possibly	YES

be adequately understood		
8 There should be an agreed on policy of who to treat	Possibly	YES
9 The total cost of finding a case should be economically balanced	YES	YES
10 Case-finding should be a continuous process, not just a "once-and-for-all project"	YES	YES

There are some screening methods to diagnose and analyze the level of cognitive impairment .Table 2 shows that the potential screening instruments for early cognitive impairment for early detection and easy management.

Table -2: Potential Screening Instruments for Early Cognitive Impairment

Instrument	**Administration Time, min**	**Items**	**Type**	**Detects MCI**
Ascertain Dementia 8 (AD8)	3	8	Informant	Yes
MiniCog	3	2	Patient	Yes

The 5 Words	3	1	Patient	No
Rapid Cognitive Screen (RCS)	3	3	Patient	Yes
Memory Impairment Screen	4	3	Patient	Yes
General Practitioners Assessment of Cognition	4–5	4(P), 6(I)	Patient/Informant	No
Kokmen Short Test of Mental Status	5	8	Patient	Yes
St Louis University Mental Status Examination (SLUMS)	7	14	Patient	Yes
7-Minute Screen (7MS)	7–10	11	Patient	No
Mini-Mental Status Exam (MMSE)	7–10	19	Patient	Yes
Telephone Interview for Cognitive Status	7–10	11	Patient	Yes
Informant Questionnaire	10–15	16	Informant	Yes

on Cognitive Decline in the Elderly (Short IQCODE)				
Addenbrook's Cognitive Exam	15	30+	Patient	Yes

3.6.1 Cognitive Impairment and Inflammatory markers

Inflammatory mediators and oxidative stress are important components in the causal mechanism of cognitive impairment(113). Super-oxide dismutase (SOD) is the key enzyme in eliminating superoxide anion so its activity represents the ability to clear oxygen radicals. Conversely, the level of blood malondialdehyde (MDA) reflects the level of cell damage caused by free radicals. Some Research indicates that compared to persons without MCI, those with MCI have significantly lower levels of blood SOD and significantly higher levels of blood MDA; these findings confirm the association between oxidative stress and cognitive impairment.

Moreover, other studies(114) have shown that the level of acetylcholinesterase (AchE) is higher among individuals with MCI compared to controls, which suggests that the functioning of the central cholinergic system is

also associated with the occurrence of MCI (114) and high sensitivity C-reactive protein (hs-CRP) has also been found to be related to MCI(115).

Recently, researchers from other countries have reported that changes in the functioning of peripheral lymphocytes is associated with changes in the immunological functioning of the brain among patients with AD(116).

Some researchers discovered that decreased levels of T-helper lymphocytes can serve as an indicator of the level of impairment of cognitive functioning(117). Other research (118) has shown that the glycogen synthase kinase-3 enzyme (GSK-3) in peripheral lymphocytes is more active among individuals with MCI or AD.

Huang's research team(119) was the first to show that the blood level of vascular endothelia growth factor (VEGF) is decreased among patients with AD or MCI, and that the decline was greater among patients with AD than among those with MCI. Chinese researchers also reported that the blood level brain-derived neurotrophic factor (BDNF) is significantly lower among individuals with aMCI than among controls(120).

Other research has found that the serum level of matrix metalloproteinase-9 (MMP-9) is higher among older individuals with metabolic syndrome who have concurrent MCI than in those who have metabolic syndrome without MCI, suggesting a relationship between serum MMP-9 and the development and severity of MCI in individuals who have metabolic syndrome. (153)

3.7 Cognitive impairment and major depression disorder

Baune at al study indicates that MDD may have negative and enduring effects on cognitive performance which is moderately related to poorer general functioning.(121)

Several symptoms of MDD (major depressive disorder) may act as mediators of cognitive impairment which includes fatigue, psychomotor retardation, mood disturbances,amotivation, and insomnia.(122)

Even though cognitive dysfunctions are present in people with MDD, It is proven that on treatment patients get relieved from the symptoms of MDD but not CI. In a study MDD patients have been followed up for 3 years and noted that during acute depressive episodes the proportion of time with cognitive complaints was reported as 94% and that still remained at 44% despite full or partial symptom remission during treatment(123)tests to analyze cognition such as for immediate memory, attention(121)and processing speed was affirmed to be inferior in patients with MDD who met ideals for remission, compared with healthy subjects. Meta-analyses demonstrates that cognitive deficits in executive function are still present in remitted patients, which may explain persistent psychosocial impairment in remission.(124)

Another study of patients with MDD treated with Ads (antidepressants) for minimum of 3 months who were considered to be partially or completely remitted,

30% to 50% reported residual cognitive symptoms which interferes with functioning.(125)

Another study reported that more than one-fourth of the impact of MDD on work loss was directly attributable to self-reported cognitive complaints (that is, difficulty concentrating, memory, understanding, and ability to think clearly(126). As a Whole, cognitive dysfunction, work, and psychosocial limitations are prevalent in patients with current and remitted depression(123).

Cognitive deficits in MDD are consistent, replicable, nonspecific, and clinically significant. The aggregated estimated effect size of cognitive deficits in MDD is small to medium. Other replicated abnormalities are in the areas of working memory, attention, and psychomotor processing speed. Mediational studies indicate that cognitive deficits may account for the largest percentage of variance with respect to the link between psychosocial dysfunction (nota bly workforce performance) and MDD. Cognitive deficits in MDD are a principal mediator of psychosocial impairment, notably workforce performance(127).

3.8 Cognitive impairment and depression

A study proposed that cognitive impairment is associated with the increasing duration of depressive episodes, which is particularly with psychotic features in the course of illness and such episodes may be the significant predictor of future impairment of cognitive function(124).

In another study it is proved that the depressed group with melancholia has a distinctly different and more impaired cognitive profile compared to those without melancholic features. Moreover, the melancholic group seems to require longer periods for cognitive recovery and this has implications for return to work and daily functioning following clinical discharge(128).

While monitoring the cognition of currently depressed and previously depressed subjects, it is found that both currently depressed and previously depressed scored significantly lower than never depressed subjects. Recurrently depressed subject's shows similarly to subjects with a single depressive episode. These outcomes indicate a mild and limited cognitive impairment during the course of a mild to moderate major depressive disorder even in young adults(129).

A study which evaluated the association between CI and MDD, in which participants were assessed clinically using the Mini International Neuropsychiatric Interview (M.I.N.I.) for the depression groups and the Diagnostic Interview for Psychoses (DIP-DM) for the control group(n=206). Measures to evaluate cognition and quality of lifes comprised the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), the Short Form-36 Health Survey Questionnaire, and the Activities/Instrumental Activities of Daily Living (ADL/IADL); employment status was also assessed in MDD.The results showed that

a) while individuals with current depression had worse cognitive performance in all domains than healthy controls, those individuals with previous depression had lasting cognitive impairments in the domains of immediate memory and attention as compared with healthy controls;

b) Individuals with current depression had lower scores in the visuospatial/constructional and attention domains and the total score than individuals with previous depression;

c) Individuals in the depression group as a whole who were currently unemployed had significantly lower scores in all domains (except attention) of cognitive function;

d) Cognitive function was not related to either physical or mental quality of life or impairments of activities of daily living (ADL, IADL);

e) That unemployment in previous depression was related to poor cognitive function similar to those with current depression. The results indicate that MDD may have detrimental and lasting effects on cognitive performance partly related to poorer general functioning.(121)

Cognitive impairments are common in young adults with major depression and anxiety disorders, although their nature remains partly unclear(130).

Another research by Halvorsen indicates a mild and limited cognitive impairment during the course of a mild to moderate major depressive disorder among relatively young adults(129).

3.9 Cognitive impairment and psychosocial behaviors

Though, some systematic reviews(131)have emphasized the limited evidence base of studies relating objective cognitive dysfunction with psychosocial functioning. Deficits in cognitive domains, including attention and processing speed, executive function, and verbal knowledge, have been correlated with some measures of psychosocial functioning(132).

Cognitive dysfunction, work, and psychosocial limitations are prevalent in patients with current and remitted depression(123). There is evidence that cognitive dysfunction in MDD may mediate impairments in psychosocial and work functioning, both during acute depressive episodes and remission, there is still a need for more rigorous studies of these relations(133).

3.10 Cognitive impairment and sleep

The first published experimental study of the cognitive performance effects of sleep deprivation in humans was reported in 1896 and involved three adults experiencing 90 hours of continuous wakefulness(134).

It has long been established that sleep deprivation destroys features of cognitive performance(135). Three categories of measurement commonly used in sleep deprivation studies include cognitive performance, motor performance, and mood(136).

Insufficiencies in daytime performance due to sleep loss are experienced globally which associated with a significant social, financial, and human cost.

Loss of sleep disturbs the daily routine by increasing micro sleeps, sleep attacks, and lapses in cognition. Various studies on sleep deprivation repeatedly shows a negative impact on mood, cognitive performance and motor function due to an increasing sleep tendency and destabilization of the waking state.

Recent experiments on chronic partial sleep deprivation, establish that profound neurocognitive deficits accumulate over time in the face of subjective adaptation to the sensation of sleepiness. Sleep deprivation accompanying with disease-related sleep fragmentation (i.e., sleep apnea and restless legs syndrome) also results in (137)

Sleep may have pro-cognitive effects and sleep deprivation affects numerous purviews of cognition. so investigating sleep quality is important factor in case of analyzing cognitive performance(138)

Virtually all forms of sleep deprivation result in increased negative mood states, especially feelings of fatigue, loss of vigor, sleepiness, and confusion. Although feelings of irritability, anxiety, and depression are believed to result from inadequate sleep, experimental evidence of the existence of these mood states following sleep deprivation in a comfortable and predictable environment is thus far lacking. These alterations in mood, however, have been observed repeatedly when sleep deprivation occurs without regard for conditions(139).

On the other hand, self-reports of fatigue and sleepiness are often blunted in chronic sleep restriction relative to the more linear effects of chronic partial sleep loss on cognitive performance(140).

An early meta-analysis suggested that the effects of sleep deprivation on feelings of fatigue and related mood states are greater than the effects on cognitive performance and motor functions(136)

Experiments found that chronic sleep restriction results in cognitive dysfunctions than subjective measures of fatigue and mood (137), although rapid versus gradual restriction of sleep can influence the rate of accumulation of cognitive deficits.(140) Neurocognitive deficits in healthy aging have been attributed to deficits in the prefrontal cortex. Both aging and sleep deprivation appear to reliably slow cognitive "throughput." (141)

Functional neuroimaging techniques such as positron emission tomography (PET) and functional magnetic resonance imaging (fMRI) have been highly used to examine the influence of sleep deprivation on brain metabolism and to relate changes in neural activity to behavioral performance decline and compensation(142).

Other tasks to analyse the effects of sleep deprivation include arithmetic calculation, verbal learning, logical reasoning, spatial navigation, inhibition control, risky decision making, and emotional processing(143).

3.11 Cognitive impairment and education

One study reported a 11.0% prevalence of MCI among individuals with a primary school education, 7.8% among those with a secondary school education, 6.7% among those with a high school education, and 5.5% among those with a college education (144).

3.12 Cognitive impairment progress to dementia

A 2015 study published in *JAMA Psychiatry*, for example, found that people with depression had an 83 percent increased risk of acquiring dementia compared with people who did not have depression and it also found that people who had depression and type 2 diabetes were at even higher risk of developing dementia, with a 117 percent increased risk compared with people who had neither condition(145). One study conducted in 2000 followed up 18 individuals with MCI and found that all of them progressed to dementia within four years(146).

Xiao and colleagues followed up individuals with MCI for three years and found that 27.7% developed dementia, compared to 0.7% in the control group(111). A long-term follow-up study of individuals with MCI by Zhu and colleagues reported that 16.5% developed dementia within five years and 42.1% developed dementia within ten years(111).

3.13 Cognitive impairment and old age:

MCI can be classified as amnestic (when there is memory impairment), amnestic multiple dominions (when there is memory loss and loss in other cognitive functions), non-amnestic (when there is loss of a cognitive function other than memory), and non-amnestic multiple domains (when there is loss of other cognitive functions other than memory) (158, 159) ,MCI can be a conversion stage to dementia, such as Alzheimer's disease or vascular dementia; however, elderly adults with MCI may expand or remain stable over the course of years.(159)

Most longitudinal studies of elderly adults with MCI have concentrated on the neuropsychological predictors of dementia and the rate of MCI conversion to dementia. Few recent studies have sought to identify the curve of cognitive decline in older adults with MCI, using different methodologies. The data showed different cognitive decline profiles in elderly adults with MCI and differences between them regarding depressive symptoms and rate of conversion to dementia. This study fortifies that, depending on the neuropsychological profile at baseline, conversion to dementia or other cognitive/behavior decline trajectory can be predicted. These data do not change the MCI definition, but provide a well understanding of the heterogeneity of MCI trajectory evolution.(160),(161)

The study of aging and dementia has led to the description of MCI. The build of MCI, particularly amnestic MCI, has stimulated research as it is a high risk group for dementia. In the past one decade, there is an exponential increase in

the epidemiology, clinical, neuroimaging, and interventional research targeting MCI. The field of cognitive aging is now affecting towards identification of asymptomatic individuals who have underlying AD pathology that can be detected by using biomarkers and neuroimaging technologies.(162)

The prevention of a disease involves detecting high risk groups; indeed, MCI constitutes a high risk state for dementia, mostly for dementia of Alzheimer's type (163)

The spectrum of cognitive decline in the elderly ranges from what can be categorized as normal cognitive decline with aging to subjective cognitive impairment to mild cognitive impairment (MCI) to dementia.(164)

There are various etiologies of MCI, and a large number of studies have been directed to ascertain the practical modalities of preserving cognition in predementia stages. Lifestyle modification, such as aerobic exercise, is an approved modality to preserve cognitive ability and decrease the rate of progression to dementia, as well as being recommended for frailty prevention.(165)

3.14 Yoga nidra

The term yoga nidra is derived from two Sanskrit words, "**yoga**" meaning "**union or one-pointed awareness**", and "**nidra**" which means "**sleep**". While practicing it, one appears to be asleep, but the consciousness will be functioning at a deeper level of awareness. Hence, YN is referred to as psychic sleep or deep relaxation with inner awareness. It is a state between sleep and wakefulness and that contacts with the subconscious and unconscious dimensions spontaneously. (23)

Yoga nidra is one aspect of pratyahara which leads to the higher states of concentration and samadhi. When one practices Yoga Nidra, it opens the deeper phases of the mind (23).

Yoga Nidra was found and formulated by Swami Satyananda Saraswati of Bihar school of yoga. In yogic system, Yoga Nidra is considered as a form of raja yoga.It belongs to the higher stages of raja yoga, since it is essentially a method of pratyahara - fifth stage of patanjali ashtanga yoga(23).

In Hatharathnavali, Yoga Nidra is said as an asana, where in the legs are wound around the neck and hands are tied on the back and lied down. This is said to improve the positive health(147).

Yoga nidra is derived from the tantras, is a powerful technique to relax consciously. It is true relaxation with awareness. It is a state of dynamic sleep. Yoga nidra is a systematic method of inducing complete physical, mental and emotional relaxation. (23)

Yogis, psychologists and physiologists alike recognize the existence of three fundamental and distinct states of individual human consciousness. These are the waking, dream and deep sleep states. Each of these states of consciousness, as well as the borderline state of yoga nidra, has been correlated with distinct patterns of electrical activity in the brain, as summarized in Table 1. (23)

In the wakeful state of awareness, the conscious mind is actively engaged with the external environment through the sensory channels of experience. During this period, fast rhythm beta waves (frequency 13-20 c.p.s.) predominate. (23)

During the dreaming state, when the subconscious mind becomes predominant, the suppressed desires, fears, inhibitions and deep-seated impressions samskaras are actively expressed. This is characterized by theta waves (frequency 4-7 c.p.s.). (23)

In the deep sleep state, the unconscious mind, source of instincts, drives and deeply buried experiences of earlier evolutionary stages, manifests. In contrast to the dream state, all mental activity and fluctuation disappears during deep sleep. In this state, the samskaras (past impressions) and vasanas (latent desires) are inactivated and the mind and body are paralyzed. Consciousness and prana alike withdraw from the individual body and mind and retreat (23)

Stage	State of consciousness	Psychological dimension	Brainwave pattern	Realm of experience
1	Awake	Conscious mind	Beta (13-20 c.p.s)	Sensory awareness, external knowledge
2	Yoga nidra	Superconscious mind	Alpha (8-12 c.p.s)	Deep relaxation, visionary states, conscious dreaming, archetypal imagery
3	Dreaming sleep	Subconscious mind	Theta (4-7 c.p.s)	Release of emotions, suppressed fears and desires
4	Deep sleep	Unconscious mind	Delta (0-4c.p.s)	Awakening of institutions and primitive drives

Table 4: State of consciousness and brainwaves patterns

It has been proved that Yoga Nidra practice was helpful in patients with Stress, anxiety and depressive symptoms(148)

Another study showed the effectiveness of *Yoga Nidra* and seated meditation in reducing anxiety and stress levels of college professors when compared to the control group, there was greater effectiveness of the Yoga Nidra intervention, regarding anxiety.(149)

From a review article, it is concluded that yoga nidra helps in various mental health problems and also good for general wellbeing(150).So mental health problems can be treated with yoga nidra alone for complete cure.

A study conducted on 100 women with depression and anxiety linked to menstruation showed that the intervention group has been benefited from yoga nidra than the control group. Hence they have concluded that YN practice is beneficial for anxiety, depression and stress.(148)

Another study proved that Yoga nidra can be a successful therapy to overcome the psychiatric morbidity associated with menstrual irregularities and other psychosomatic disorders.(151)

A research have proved that intervention group which practiced yoga nidra for six months, showed significant decrease in the degree of depressive symptoms, those symptoms are calculated according to the psychological general wellbeing Index.(152)

Study by rani et al proved that Yoga Nidra is a successful therapy to overcome the psychiatric morbidity and so it can be prescribed as an adjunct to conventional drug therapy for menstrual dysfunction.(148)

4.0 METHODOLOGY

The methodological process involved in the following study is described in detail in this chapter.

4.1 STUDY DESIGN:

The study employs prospective intervention study. The structure questionnaire will be used to collect the demographic information and Mini–Mental State Examination (MMSE) scale will be used to collect the cognitive impairment details. The yoga nidra will be provided only to those subjects who score less than 24 on MMSE scale.

4.2. ETHICAL CONSIDERATIONS

4.2.1 ETHICAL CLEARANCE

Ethical clearance was sought from the Institutional Ethics Committee prior to the start of the study and the approval for the same was granted.

4.2.2 WRITTEN INFORMED CONSENT

Subjects who fulfilled inclusion criteria were appraised about the purpose of the studyand their rights as research subjects. Informed consent form was administered in English.

As all the subjects understood spoke English, there was no requirement of translating the signed informed consent form into native language i.e., Tamil. Adequate time was given to each patient to go through the information sheet and their queries were answered.

Their right to withdraw anytime from the study and the need for willingness to participate voluntarily in the study was explained. All the subjects expressed their willingness to participate in the study by giving a signed informed consent. (A sample information sheet and consent form is enclosed as Annexure 3)

Figure-6: The practitioner getting prior consent from the participant

4.3 SUBJECTS:

The study population will be selected from out-patient (OP) department and in-patient department (IP) in Government yoga and naturopathy medical college and hospital, chennai. Totally 40 subjects of age group between 30 to 55years old will be selected for this study. After obtaining informed consent, the samples will be selected conveniently and the questionnaires will be administrated. The scores will be calculated at same time. Based on the MMSE score, the subjects will be

selected for Yoga intervention. Those who score less than 24 will be selected for this intervention. 30 minutes Yoga nidra will be given for 2 months for every alternative day. The complete Yoga Nidra instructions will be given to the selected subjects (Annexure 1). The investigator will supervise the subjects for whole 2 months.

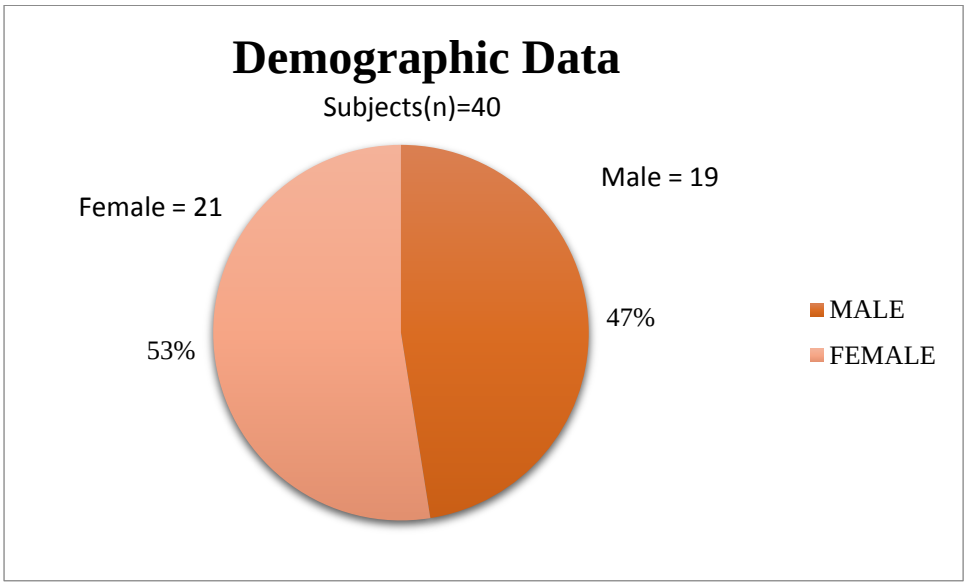


Figure-7: Pie diagram representing the gender

Out of 40 subjects included in this study to analyse the impact of **Yoga nidra** on Cognitive impairment, 21 subjects (53%) were females and 19 subjects (47%) were males.

4.4 STUDY PERIOD:

12 months

4.5 SUBJECT SELECTION:

Taking the subjects who are satisfying the following inclusion & exclusion criteria

4.5.1 Inclusion Criteria

Subjects will be included if they fulfill following criteria

- Age group: 30 to 55 years
- Both sexes
- People who are ready to give their consent
- the education qualification will be considered, those who completed middle school (8th standard)

4.5.2 Exclusion Criteria

Subjects will be excluded if they have

- Significant organic pathology like head injury, seizure, mental retardation, substance abuse.
- those who are having physical health problems which affects functioning of daily living of the individual during past one year,
- those who are having problems with speech, hearing, and vision, which can impede the interview,
- Females in the post-partum period,
- Bed ridden patients and
- Those who are not willing also will be excluded from this study.

4.6 Sample Size and sampling

Based on 80% power and error 5%, 40 subjects were required. All subjects attending the hospital during the study period will be recruited into the study for screening, based on MMSE score, the subject will be selected for intervention.

4.7 Withdrawal Criteria:

All subjects are free to withdraw from participation in the study at any time, for any reason, specified or unspecified, and without prejudice to further yogic practices. Subjects who are withdrawn from the study will not be replaced.

4.8 Methodology:

A single group pre-post study design was adopted in this study. All the recruited subjects' were given yoga nidra for 30 minutes for every alternate day for about 3 months. The scores of MMSE scale and DASS scale were taken before and after the intervention.

Forty healthy volunteers of age group between 30 -55 years will be recruited in this study. The subjects are general public from Government of Yoga and Naturopathy Medical College hospital, Chennai-106. After obtaining informed consent, the screening will be done using MMSE scale. Those who score less than 24 in MMSE score will be recruited for this study .after that the selected indivuals will be give yoga nidra practice. Post interventional MMSE score and DASS score will be recorded.

4.9 Duration of the entire Intervention Procedure:

Training period: 1 week

Intervention period: 2 months

Frequency of practice: on alternate days

Duration of practice: minimum of 30 min

4.10 Procedure for Yoga nidra

4.10.1 Getting ready for Yoga nidra:

The following instructions were given to the subjects

- Lie down on the back in shavasana
- Keep your legs apart
- Hands away from the body
- Fingers semiflexed
- Eyes closed
- Relax and
- Prepare your mind for the practice of yognidra.

4.11 Yoga Nidra

Instructions Yoga Nidra were given in the following manner

4.11.1 Preparation

- Get ready for Yoga Nidra.
- Lie down on your back on the floor and adopt the pose called shavasana.

- In this position the body should be straight from head to toe, the legs slightly apart and the arms away from the body, with the palms of the hands turned upwards.
- Take deep breath and as you breathe out feel the cares and worries of the day flow out of you. In the practice which follows, you are going to develop the feeling of relaxation in the body.
- During Yoga Nidra, you are functioning on the levels of hearing and awareness, and the only important thing is to follow the voice of the instructor.

4.11.2 Relaxation

- Now bring about a feeling of inner relaxation in the whole body; concentrate whole body and become aware of the importance of complete stillness (pause).
- Develop awareness of your body from the top of the head to the tips of the toes and mentally repeat the mantra O-o-o-m-m-m. Experience complete stillness and complete awareness of the whole body again O-oo- m-m-m (pause).

4.11.3 Resolve

- At this moment you should resolve to yourself

. 

Figure-8: A participant performing Yoga nidra

- The resolve will have to be very simple; it should be a short, positive statement in simple language stated three times with awareness, feeling and emphasis.

- The resolve you make during Yoga Nidra is bound to come true in your life (pause).

4.11.4 Rotation of consciousness

- We now begin rotation of consciousness, rotation of awareness by taking a trip through the different parts of the body (pause), as quickly as possible the awareness is to go from part to part.
- Repeat the part in your mind and simultaneously become aware of that part of the body.
- Become aware of the right side, left side, back, front, and major parts of the body (pause).

4.11.5 Breathing

- Become aware of your breath.
- Feel the flow of your breath in and out of your lungs (pause).
- Now concentrate your awareness on the movement of your navel area. Concentrate on your navel movements (pause).
- Your navel is rising and falling slightly with every breath, with each and every breath it expands and contracts (pause).
- Now start counting your breaths backwards from 27 to 1, like this: 27 navel rising, 27 navel falling, 26 navel rising, 26 navel falling, 25 navel rising, 25 navel falling, and so on.

- Say the words and numbers mentally to yourself as you count your breaths (pause).

4.11.6 Image visualization

- Stop counting and leave your breath awareness;
- we now come to visualization.
- A number of different things will be named and you should try to develop a vision of them on all levels of feelings, awareness, emotions, imagination, as best you can.

4.11.7 Resolve

- Now this is the time to repeat your resolve.
- Repeat the same resolve that you made at the beginning of the practice, do not change it, repeat the resolve three times with full awareness and feeling (pause).

4.11.8 Finish

- Relax all efforts, draw your mind outside and become aware of your breath (pause), become aware of the natural breath, awareness of the whole body and awareness of breathing (pause).
- Your body is lying totally relaxed on the floor you are breathing quietly and slowly. Develop awareness of your body from the top of the head to the tip of the toes and say mentally in your mind O-o-o-m-m-m (pause).
- Please take your time, do not hurry.

- Start moving your body. When you are sure that you are wide awake, sit up slowly and open your eyes.
- The practice of Yoga Nidra is now complete.(23)

4.12 Time period for data collection:

1. Base line (before): Both MMSE and DASS scores were measured prior to the intervention studies

2. At the end of 2nd month: Both MMSE and DASS scores were measured during the intervention/training period

4.13 DATA EXTRACTION

4.13.1 MMSE score and DASS score:

Data variables to be collected are shown in relation to study objectives.

Primary objective:

- To assess the impact of Yoga Nidra on cognitive impaired subjects.
- The MMSE scale will be used to assess before and after Yoga nidra training: MMSE scale will be used to collect the information regarding the cognitive impairment.
- The **Mini–Mental State Examination** (**MMSE**) or **Folstein test** is a 30-point questionnaire that is used extensively in clinical and research settings to measure cognitive impairment.
- It is commonly used in medicine and allied health to screen for dementia.

- Any score greater than or equal to 24 points (out of 30) indicates a normal cognition.

- Below 24, scores can indicate severe (≤9 points), moderate (10–18 points) or mild (19–23 points) cognitive impairment. (Annexure 1)

Figure-9: MMSE score assessment on study participants

Secondary Objective:

- To document the improvement in depression/ anxiety/ stress level in impaired subjects:

- The Depression, Anxiety Stress Scale (DASS-21) scale (Annexure 2) will be used to assess the level of depression, Anxiety and stress level in pre and post intervention.
- The subjects will be assessed based on the scores.
- The scores will be used to see the associations with the demographic and socio economic variables

4.14 Statistical Analysis:

Normality checked through Shapiro wilk test, parameters and non parametersanalysed through paired sample t test.

4.15. Ethical issues:

Ethics approval

Permission for the study will be sought from Dr MGR medical University Institutional Ethical committee. Informed consent will be obtained from the eligible subjects and those consenting will be interviewed.

Data confidentiality

No names will be recorded in data collection forms. Data will be stored in password protected computers.

5.0 RESULTS

5.1 Statistical analysis

The results for the following studies were statistically determined for both MMSE and DASS score and the results were graphically plotted by R-statistical software. The following data for each subsets were expressed Mean± SD.

5.1.1 Effect of Yoga nidra in MMSE score

Comparison of Mean MMSE score during the baseline and at the end of second month was analyzed by Shapiro wilk test, followed by paired simple t test for determining the variation in the overall mean during the study period

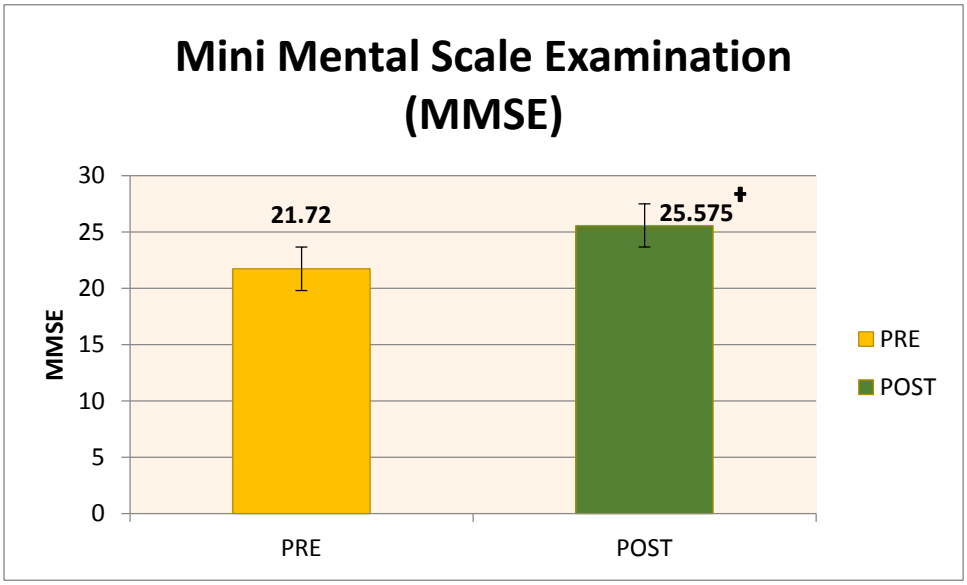
MMSE		
	PRE	POST
MEAN	21.72	25.57
SD	1.03	1.33
df	39	
t Stat	-26.43072231	
p Value	0.0001	

Table 3: Representation of impact of Yoga nidra on MMSE score of the study participants

The resultant Table 3 represents the overall impact of Yoga nidra on the MMSE score of the study participants. The overall mean of the MMSE score readings, of the study participants mean 21.72±1.03 were significantly improved

to 25.57±1.33. The p value is significant (0.0001). Thus it proves that the MMSE score is significantly reduced in case of practicing Yoga nidra regularly.

The below Figure 8 provides a graphical illustration, representing the overall changes observed in the cardiovascular parameters, before, during and after the completion of intervention.



+indicates significance at p<0.0001

Figure-10: Graphical representation of impact of MMSE score

5.1.2 Effect of Yoga nidra in Depression score

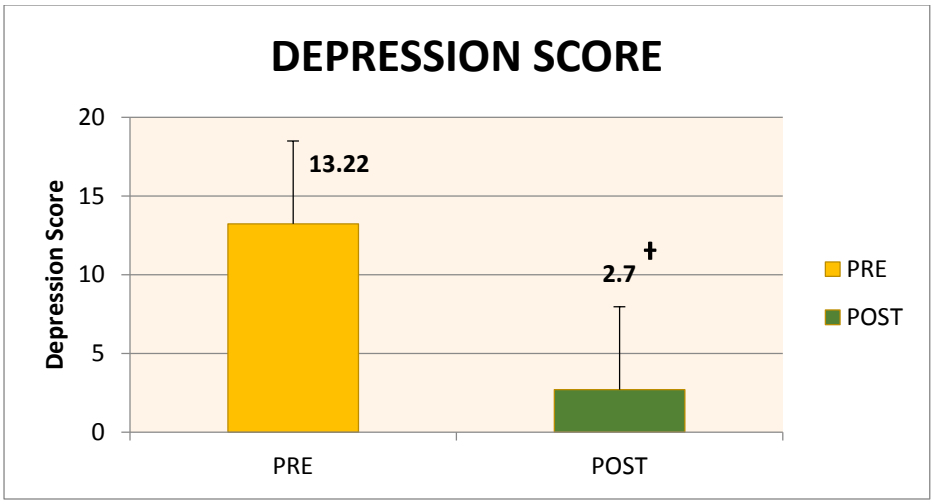
Comparison of Mean depression score collected from DASS score during the baseline and at the end of second month was analyzed by Shapiro wilk test,

followed by paired simple t test for determining the variation in the overall mean during the study period.

DEPRESSION SCORE		
	PRE	POST
Mean	13.225	2.7
SD	2.939	0.757
t Stat	25.9827807	
df	39	
p Value	0.00001	

Table 4: Representation of impact of Yoga nidra on Depression score of the study participants

The resultant Table 4 represents the overall impact of Yoga nidra on the Depression score of the study participants. The overall mean of the score of Depression readings calculated from DASS score of the study participants mean 13.225±2.939were significantly improved to 2.7±0.757. The p value is significant (0.00001). Thus it proves that the Depression score is significantly reduced in case of practicing Yoga nidra regularly.



+ indicates significance at p<0.00001

Figure-11: Graphical representation of impact of Depression score

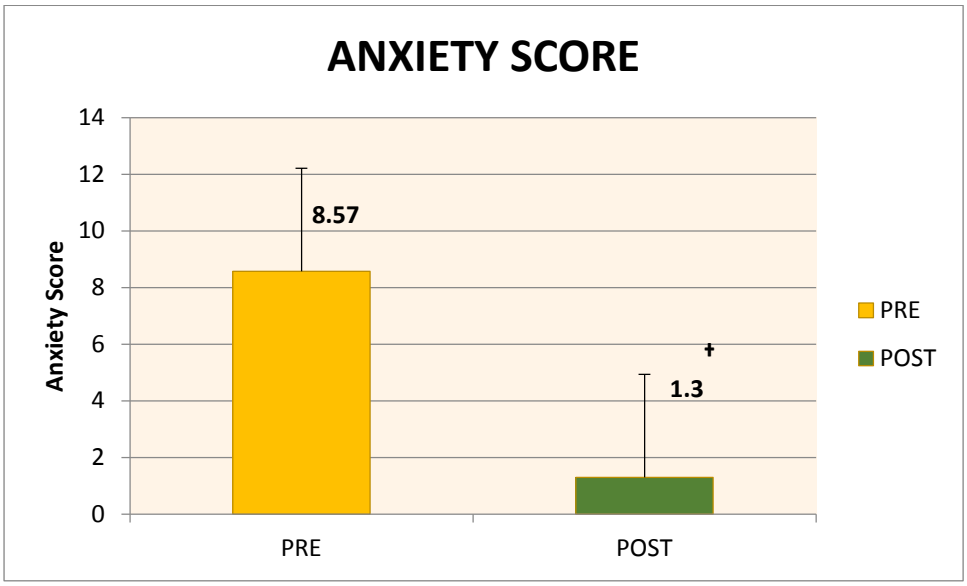
5.2.3 Effect of Yoga nidra in Anxiety score

Comparison of Mean Anxiety score collected from DASS score during the baseline and at the end of second month was analyzed by Shapiro wilk test, followed by paired simple t test for determining the variation in the overall mean during the study period.

ANXIETY SCORE		
	PRE	POST
MEAN	8.575	1.3
SD	3.04	1.3
df	39	
t Stat	20.52555742	
p Value	0.0001	

Table 5: Representation of impact of Yoga nidra on Anxiety score

The resultant Table 5 represents the overall impact of Yoga nidra on the Anxiety score collected from DASS score of the study participants. The overall mean of the score of Anxiety readings calculated from DASS score of the study participants mean 8.575±3.04were significantly improved to 1.3±1.3. The p value is significant (0.0001). Thus it proves that the Anxiety score is significantly reduced in case of practicing Yoga nidra regularly.



+ indicates significance at p<0.0001

Figure-12: Graphical representation of impact of Anxiety score

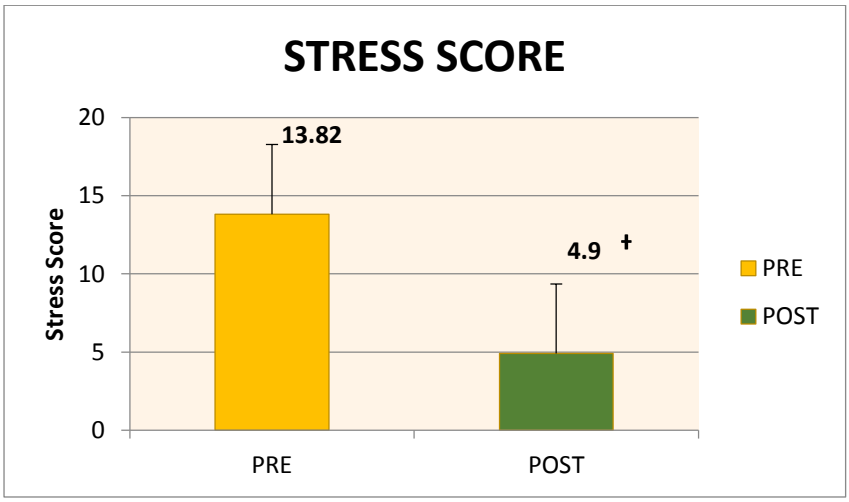
5.2.4 Effect of Yoga nidra in stress score

Comparison of Mean stress score collected from DASS score during the baseline and at the end of second month was analyzed by shapirowilk test, followed by paired simple t test for determining the variation in the overall mean during the study period.

STRESS SCORE		
	PRE	POST
MEAN	13.82	4.9
SD	3.7	2.18
df	39	
t Stat	23.1048076	
p Value	0.0001	

Table 6: Representation of impact of Yoga nidra on stress score

The resultant Table 6 represents the overall impact of Stress on the DASS score of the study participants. The overall mean of the score of Stress scores calculated from DASS score of the study participants mean 13.82±3.7were significantly improved to 4.9±2.18. The p value is significant (0.0001). Thus it proves that the stress score is significantly.



+ indicates significance at p<0.0001

Figure-13: Graphical representation of impact of Stress score

6.0 DISCUSSION

Relaxation has also been suggested as a potential preventative measure for burnoutrelated stress based on the ancient Tantric practice of nyasa, in which a mantra is repeated mentally at with concentration at specific parts of the body (153).

The yogic texts describe a state of consciousness called turiya, or the fourth state, which is a state of consciousness beyond waking, sleeping, and dreaming (153). This state is considered to lead to Samadhi, or bliss.Researchers have reported significant decreased in rage, anxiety, and emotional reactivity, increased joy and ability to manage stress, and increased sleep. (154)

In a study by **Eastman-Mueller et al., 2013**(155), a sample of sixty-six college students participated in an 8-week YogaNidra intervention. Researchers assessed changes in worry and perceived stress. The data suggests that the intervention was helpful in reducing students' worry and stress. There is evidence to suggest that yoga, meditation, and relaxation have positive effects on Participants were asked to complete a baseline assessment using the Perceived Stress Scale(156)**.**

The PSS-10 is a widely used 10-item scale used to measure the degree to which events in one's life have been stressful, overwhelming, and unpredictable in the past month on a 0-4 Likert scale. It measures the perceived experience of stress, rather than objective variables that may contribute to increased stress. Participants were not asked about events in their life which may have contributed

to stress, but rather the perceived experience of stress in the last month. The PSS has been measured and tested effectively for reliability and validity(156).

The relaxation response, a physiological phenomenon considered to be the opposite of the fight-or flight stress response, is of increasing interest in the medical field as a preventative and alternative treatment for stress-related disorders. Methods of inducing the relaxation response include some forms of yoga or meditation, progressive muscle relaxation, and stress management training.

The Relaxation Response Resiliency Program is a standardized, 8-week program incorporating a variety of modalities to increase relaxation and resiliency. In a recent study, Stahl and colleagues found that a year-long intervention incorporating these various methods to increase the relaxation response, including yoga and meditation, decreased billable medical encounters by 43 percent. In addition to stress, researchers have suggested that relaxation may have positive effects on cardiovascular health (155)

Yoga nidra may have positive effects in medical patients. Two studies have looked at the effect of Yoga nidra on psychological and physiological symptoms associated with menstrual disorders and found significant positive results(148).
A study (30)evoluated the effects of Yoganidra on perceived stress levels in medical patients with cancer and multiple sclerosis and found the perceived stress was significantly reduced in the 12 participants after the 6-week program.

A study conducted by ferreira et al 2018 to evaluate the effect of yoga nidra on cognition and mental health conducted on college professionals has proved that yoga nidra practices reduces stress and anxiety and thus improves mental health (149)

Thus yoga nidra practices balances the mind and body. It helps in reducing stress, anxiety and also depression. So yoga nidra will be much more useful to treat mental health issues. It has no side effects and easily assessable by the participants itself and also easily understandable. Hence reducing stress and depression will simultaneously reduce the risk factors of most of the communicable diseases.

7.0 CONCLUSIONS

The present study confirms that by practicing “Yoga nidra” relieves stress, depression and anxiety completely and thus improves the mental health promotes cognition. Yoga nidra is one of the forms of relaxation techniques in yoga practices, which is a practice of “sleep with awareness”. One should relax but not sleep during the practice of Yoga nidra. Depression, stress and anxiety denote the range of mental health of the person. If the mental health is low, the person will get affected by many non communicable diseases. Nowadays the risks pertaining to CVD related issues were raising over the years(157). The score of MMSE scale denotes the range of cognitive activities and the score of DASS scale denotes the level of Depression, Anxiety and Stress in individuals. The practice of Yoga nidra improves MMSE score and thus improves cognitive activity. Same way, Yoga nidra practice reduces DASS score, which in turn reduces Depression, Anxiety and Stress levels in individuals. Through assessing these parameters among the study participants/subjects over the period of 2 months (8 weeks) showed significant improvement, thus exhibiting the effectiveness of practicing Yoga nidra.

LIMITATIONS:

- The current study was a pilot study comprising only of minimal number of subjects.
- Only questionnaries was used for analysis in this study
- The outcome variable used in the study, cannot be inferred, or taken as an overall mean, since the age and gender related factors could vary.
- Randomization was not done.

RECOMMENDATIONS:

The same study can be conducted on a larger population with suitable study design and some objective kind of outcome variables could be included to validate the current results.

8.0 SUMMARY

The study's objective was to determine the impact of Yoga nidra in improving the cognition and MMSE and DASS score. The causes for cognitive impairment in recent days are due to stress / anxiety / depression even in adults. Poor lifestyle, stress filled environment are contributing factors behind Cognitive impairment.The term yoga nidra is derived from two Sanskrit words, "yoga" meaning "union or one-pointed awareness", and "nidra" which means "sleep". While practicing it, one appears to be asleep, but the consciousness will be functioning at a deeper level of awareness. Hence, YN is referred to as psychic sleep or deep relaxation with inner awareness. It is a state between sleep and wakefulness and that contact with the subconscious and unconscious dimensions spontaneously. Many literature studies has witnessed the efficacy of practicing relaxation has reduced stress / depression / anxiety levelsin individuals.

The following study was intended majorly towards determining that the regular practises of Yoga nidra could facilitate in improving the cognition and reduces depression / stress / anxiety levels. The study was conducted among the cognition impaired study participants over a total period of 60 days. The baseline measurements were monitored initially for evaluating the actual difference in the MMSE score and DASS score. The entire study was conducted for a total period of 2 months. MMSE and DASS scores were assessed both before giving intervention and also at the end of 2 months time period. From the observed study,

the participants who practiced Yoga nidra exhibited significant improvement in their overall MMSE score and DASS score.

The overall mean of the MMSE score readings, of the study participants mean 21.72±1.03were significantly improved to 25.57±1.33. The p value is significant (0.0001).Thus it proves that the MMSE score is significantly reduced in case of practicing Yoga nidra regularly. The overall mean of the score of Depression readings calculated from DASS score of the study participants mean 13.225±2.939were significantly improved to 2.7±0.757. The p value is significant (0.00001).Thus it proves that the Depression score is significantly reduced in case of practicing Yoga nidra regularly.

The overall mean of the score of Anxiety readings calculated from DASS score of the study participants mean 8.575±3.04 were significantly improved to 1.3±1.3. The p value is significant (0.0001).Thus it proves that the Anxiety score is significantly reduced in case of practicing Yoga nidra regularly.

The overall mean of the score of Stress scores calculated from DASS score of the study participants mean 13.82±3.7were significantly improved to 4.9±2.18. The p value is significant (0.0001).Thus it proves that the stress score is significantly reduced in case of practicing Yoga nidra regularly.

From the overall study's outcome exhibited that regular practice of Yoga nidrahad a significant improvement in Cognitive functions and also reduces Depression/ Anxiety/ Stress levels in individuals. Through performing Yoga nidra and other Yogasanas would improve the lifespan of individuals significantly.

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10.0 ANNEXURE

Annexure 1: Mini Mental State Examination (MMSE) scale

I. **ORIENTATION** (Ask the following questions; correct = ☑)	**Record Each Answer:**	(Maximum Score = 10)
What is today's date?	Date (eg, May 21)	1 ☐
What is today's year?	Year	1 ☐
What is the month?	Month	1 ☐
What day is today?	Day (eg, Monday)	1 ☐
Can you also tell me what season it is?	Season	1 ☐
Can you also tell me the name of this hospital/clinic?	Hospital/Clinic	1 ☐
What floor are we on?	Floor	1 ☐
What city are we in?	City	1 ☐
What county are we in?	County	1 ☐
What state are we in?	State	1 ☐
II. IMMEDIATE RECALL	(correct = ☑)	(Maximum Score = 3)
Ask the subject if you may test his/her memory. Say "ball, "flag," "tree" clearly and slowly, about on second for each. Then ask the subject to repeat them. Check the box at right for each correct response. The first repetition determines the score. If he/she does not repeat all three correctly, keep saying them up to six tries until he/she can repeat them	Ball	1 ☐
	Flag	1 ☐
	Tree	1 ☐
		NUMBER OF TRIALS: _____
III. **ATTENTION AND CALCULATION**		
A. Counting Backwards Test	(Record each response, correct = ☑)	(Maximum Score = 5)
Ask the subject to begin with 100 and count backwards by 7. Record each response. Check one box at right for each correct response. Any response 7 or less than the previous response is a correct response. The score is the number of correct subtractions. For example, 93, 86, 80, 72, 65 is a score of 4; 93, 86, 78 70, 62, is 2; 92, 87, 78, 70, 65 is 0.	93	1 ☐
	86	1 ☐
	79	1 ☐
	72	1 ☐
	65	1 ☐
B. Spelling Backwards Test		
Ask the subject to spell the word "WORLD" backwards. Record each response. Use the instructions to determine which are correct responses, and check one box at right fore each correct response.	D	1 ☐
	L	1 ☐
	R	1 ☐
C. Final Score	O	1 ☐
Compare the scores of the Counting Backwards and Spelling Backwards tests. Write the greater of the two socres in the box labeled FINAL SCORE at right, and use it in deriving the **TOTAL SCORE**.	W	1 ☐
		FINAL SCORE_____ (Max of 5 or Greater of the two Scores)

IV. **RECALL**	(correct = ☑)	(Maximum Score = 3)
Ask the subject to recall the three words you previously asked him/her to remember. Check the Box at right for each correct response.	Ball	1 ☐
	Flag	1 ☐
	Tree	1 ☐
V. Language	(correct = ☑)	(Maximum Score = 9)
Naming	Watch	1 ☐
Show the subject a wrist watch and ask him/her what it is. Repeat for a pencil.	Pencil	1 ☐
Repetition		
Ask the subject to repeat "No, ifs, ands, or buts."	Repetition	1 ☐
Three -Stage Command		
Establish the subject's dominant hand. Give the subject a sheet of blank paper and say, "Take the paper in your right/left hand, fold it in half and put it on the floor."	Takes paper in hand	1 ☐
	Folds paper in half	1 ☐
	Puts paper on floor	1 ☐
Reading		
Hold up the card that reads, "Close your eyes." So the subject can see it clearly. Ask him/her to read it and do what it says. Check the box at right only if he/she actually closes his/her eyes.	Closes eyes	1 ☐
Writing		
Give the subject a sheet of blank paper and ask him/her to write a sentence. It is to be written sponataneously. If the sentence contains a subject and a verb, and is sensible, check the box at right. Correct grammar and punctuation are not necessary.	Writes sentence	1 ☐
Copying		
Show the subject the drawing of the intersecting pentagons. Ask him/her to draw the pentagons (about one inch each side) on the paper provided. If ten angles are present and two intersect, check the box at right. Ignore tremor and rotation.	Copies pentagons	1 ☐

DERIVING THE TOTAL SCORE

Add the number of correct responses. The maximum is 30.	TOTAL SCORE _____

Annexure 2 :Depression, Anxiety and Stress Scale (DASS21)

DASS21	*Name:*	*Date:*			

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all

1 Applied to me to some degree, or some of the time

2 Applied to me to a considerable degree, or a good part of time

3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3

7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3

21	I felt that life was meaningless	0	1	2	3

Annexure 3:

INFORMED CONSENT FORM

Title of the study **:** "**Impact of yoga nidra on cognitive impairment: An interventional study**"

Name of the Participant **:**

Name of the Principal Investigator **:** Dr.K.S Dhamodhini

Name of the Institution **:**Government Yoga & Naturopathy Medical College&Hospital,Chennai – 600 106

Documentation of the informed consent

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in

1. I have read and understood this consent form and the information provided to me.

2. I have had the consent document explained to me.

3. I have been explained about the nature of the study.

4. I have been explained about my rights and responsibilities by the investigator.

5. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.

6. I have been advised about the risks associated with my participation in this study.

7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.

8. I have not participated in any research study within the past _____month(s).

9. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.

10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.

12. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

13. I have understood that my identity will be kept confidential if my data are publicly presented.

14. I have had my questions answered to my satisfaction.

15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

For adult participants:

Name and signature / thumb impression of the participant (or legal representative if participant incompetent)

Name _____ Signature_____

Date_____

Name and Signature of impartial witness (required for illiterate patients):

Name _____ Signature_____

Date_____

Address and contact number of the impartial witness:

Name and Signature of the investigator or his representative obtaining consent:

Name _____ Signature_____

Date_____